Experiences of DARWIN EU –
Swedish Medical Products Agency
Gothenburg University

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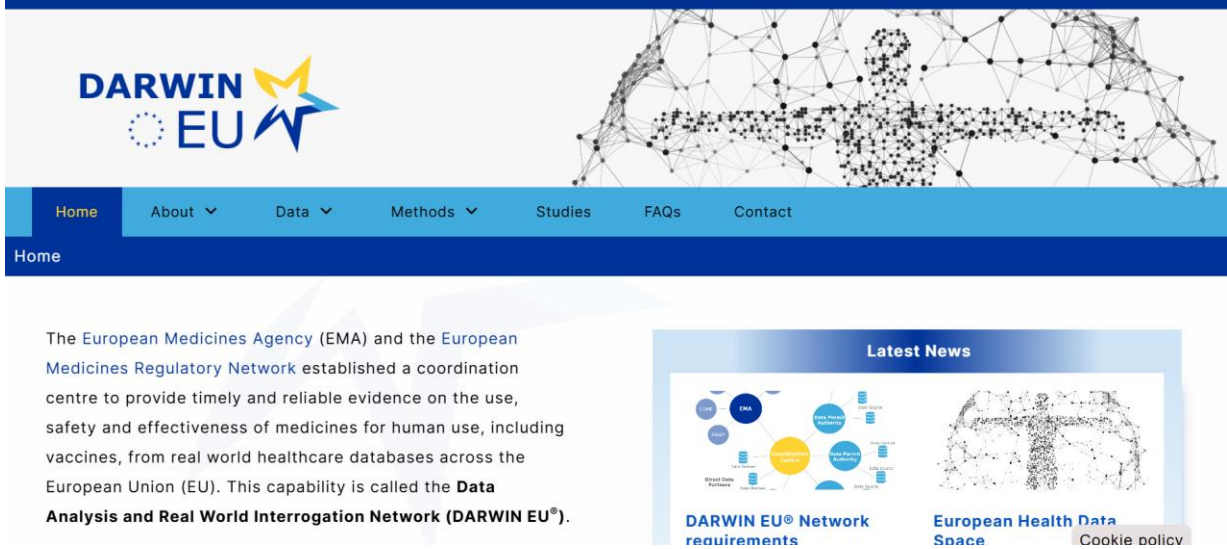
LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

DARWIN EU

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Erasmus MC
University Medical Center Rotterdam

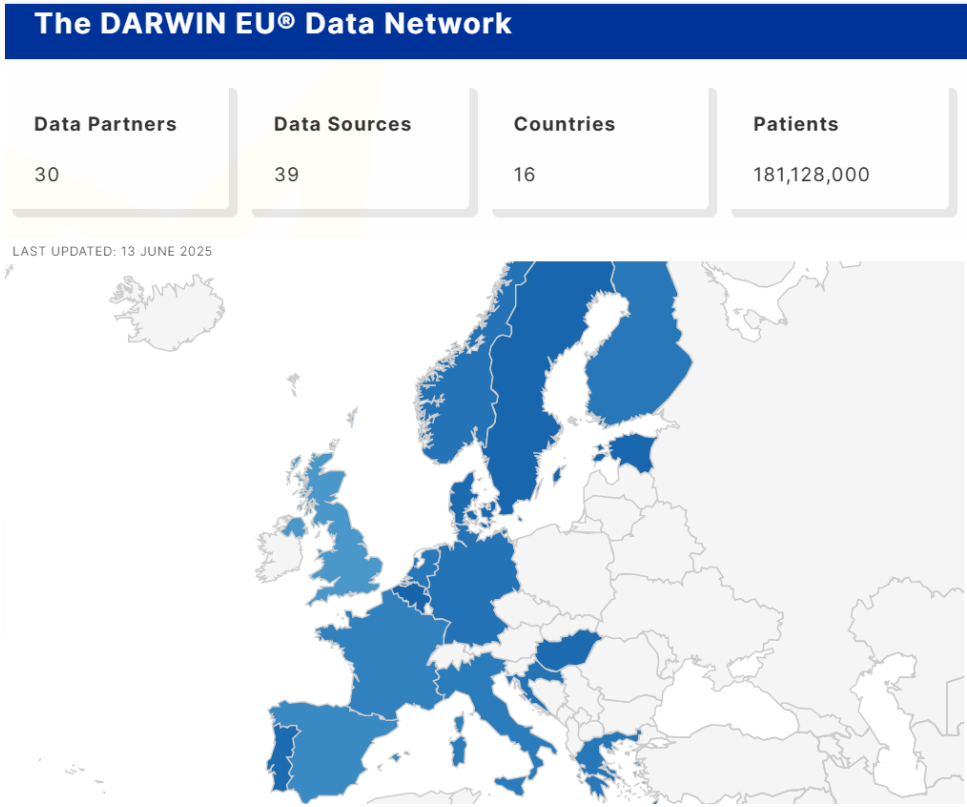


European Medicines Agency

Erasmus University, Rotterdam (DARWIN EU coordination centre)

High-quality, validated real-world data on the uses, safety and efficacy of medicines

DARWIN EU



- EMA frames a research question and together with the Coordination Centre, evaluates the relevance and feasibility
- The Coordination Centre develops the study protocol and identifies appropriate data sources
- Data partners need to obtain the mandatory ethics approval
- The data partners run the code on their own databases and provides aggregated results
- The Coordination Centre checks the quality of the study data and performs additional data analysis steps and interpretation
- The Coordination Centre compiles the results and is responsible to draft the study report for submission to EMA for approval.

DARWIN EU – type of studies

	Category	Description
	Off-The-Shelf Studies	These are mainly characterisation questions that can be executed with a generic protocol. This includes studies on disease epidemiology, for example the estimation of the prevalence or incidence of health outcomes in defined time periods and population groups, or drug utilization studies at the population or patient level.
	Complex Studies	These are studies requiring development or customisation of specific study designs, protocols, analytics and phenotypes. This includes studies on the safety and effectiveness of medicines and vaccines.
	Routine Repeated Analyses	Routine analyses based on Off-The-Shelf or Complex Studies (see above), which are repeated with a pre-specified regularity (e.g. yearly)
	Very Complex Studies	Studies which cannot rely only on electronic health care databases, or which require complex and/or novel methodological work

Swedish team for DARWIN EU

	Fredrik Nyberg	MD, PhD,	Professor, PI	GÖTEBORGS UNIVERSITET
	Huiqi Li	MSc, PhD	Associate Professor	GÖTEBORGS UNIVERSITET
	Rickard Ljung	MD, PhD,	Professor, PI	LÄKEMEDELSVERKET SWEDISH MEDICAL PRODUCTS AGENCY
	Marcel Ballin	MSc, PhD	Epidemiologist	LÄKEMEDELSVERKET SWEDISH MEDICAL PRODUCTS AGENCY
	Mats Talbäck	MSc, PhD	Statistician	LÄKEMEDELSVERKET SWEDISH MEDICAL PRODUCTS AGENCY

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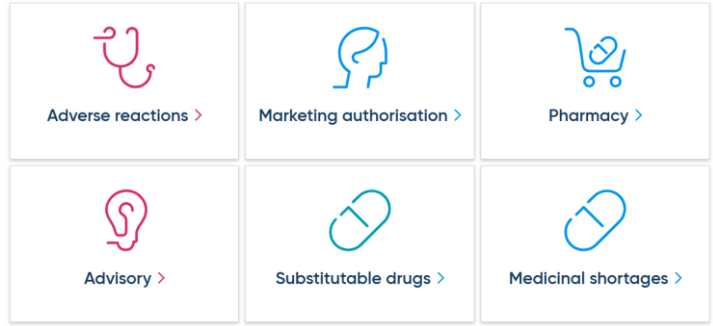


The Swedish Medical Products Agency is the national authority responsible for regulation and surveillance of the development, manufacturing and sale of pharmaceuticals and other medicinal products.

The Swedish Medical Products Agency is the **Swedish node for DARWIN EU**

Gothenburg University

School of Public Health and Community Medicine,

Institute of Medicine, Gothenburg University.

Lead by Professor Fredrik Nyberg

Is the **Swedish DATA PARTNER for DARWIN EU**

and primary research partner to SMPA for DARWIN-related projects

HI-SPEED

HI-SPEED (Health Impact - Swedish Population Evidence Enabling Data-linkage)

GÖTEBORGS UNIVERSITET

HI-SPEED
RESEARCH PROJECT
(Health Impact–Swedish Population Evidence Enabling Data-linkage)

- Research project focused on pharmacoepidemiological research questions incl. DARWIN-related
  - Ethics in place for many questions, and updated as required
- All 11.7 million residents in Sweden since 2015
- Linked to relevant Swedish national and regional health data registers, and to sociodemographic data, updated several times annually, with most data since 2015.
  - Medicines are coded with ATC and NPLID (National Product ID)
  - ICD10-SE is used for diagnoses
  - Swedish procedure coding system (KVA) is used for clinical procedures (related to NOMESCO)
- The data have been mapped to the OMOP CDM v5.4 and the OMOP standard vocabularies (SNOMED, RxNorm, LOINC).

Ex. Swedish participation finalized studies

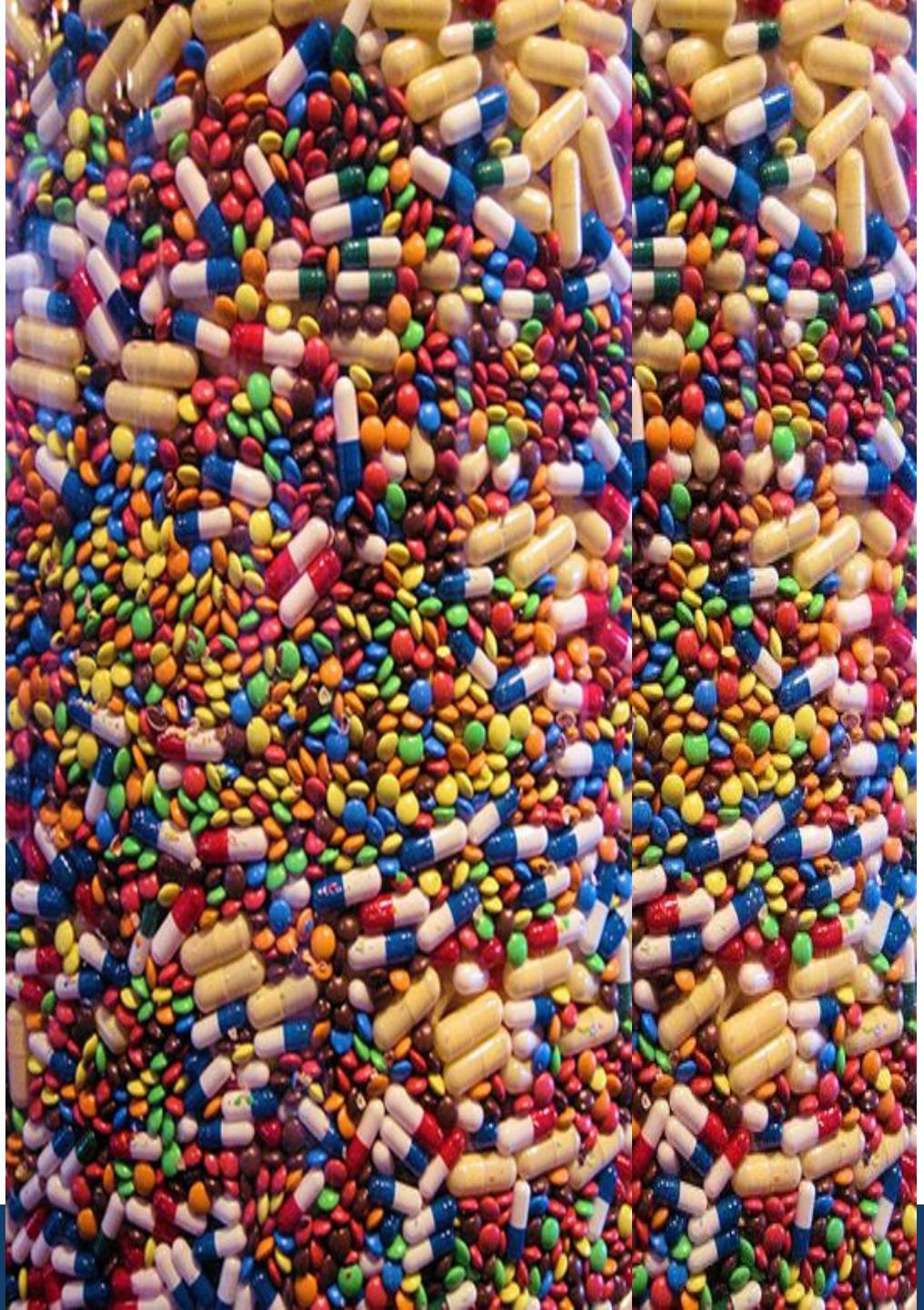
- Study P3-C3-011 DARWIN EU® - Incidence, period prevalence, and characterisation of individuals with paediatric pulmonary arterial hypertension
- Study P4-C2-002: DARWIN EU® Paracetamol prescribing and paracetamol overdose in Europe: a descriptive analysis of trends and patients characteristics
- Study P4-C1-005: DARWIN EU® Paediatric Pulmonary Arterial Hypertension disease epidemiology and treatment characterization
- Study P4-C2-001 DARWIN EU® RR Drug utilization study of prescription opioids

Reflections of first 6 months in DARWIN EU in Sweden

- High upfront **E**xtract, **T**ransform, **L**oad effort
  - OMOP mapping has to be done by each data partner with a research project based on similar linked register data (often of public origin)
  - No standardized mapping done by Government agencies in Sweden (yet)
- Variable vocabulary coverage across countries
  - Country and Regional differences in coding
- Date quality /versioning / maintenance burden
  - OMOP-version fixed throughout a project
  - If data updates twice a year:
    - Several projects in parallel running for 6-12 months
    - Duplicate databases fixed on specific version

Reflections of first 6 months cont.

- Projects decided on short notice
  - Immediate ethical vetting
  - Short time to assess protocol
- Script running not always smooth
  - Setting up environment can be troublesome, especially on secure servers.
- Result reviewing can be cubersome
- Outputs are reports to EMA
- Very seldom so far sufficient focus on developing scientific papers
  - Difficult for fulltime researcher dependent on academic achievement
- Limited funding
  - 7 000 Euro per study (14 000 Euros for complex studies)



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